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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,838	02/02/2005	Daniel W. Chan	56792(71699)	1171
21874 7590 04/30/2008 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
EXAMINER				
HARRIS, ALANA M				
ART UNIT		PAPER NUMBER		
1643				
MAIL DATE		DELIVERY MODE		
04/30/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/500,838

**Applicant(s)**

CHAN ET AL.

**Examiner**

Alana M. Harris, Ph.D.

**Art Unit**

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-5, 9-12, 34, 39, 40 and 62 is/are pending in the application.
- 4a) Of the above claim(s) 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-5, 9-12, 34, 39 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendments and Arguments***

1. Claims 3-5, 9-12, 34, 39, 40 and 62 are pending.  
Claim 40, drawn to non-elected inventions are withdrawn from examination.  
Claims 3 and 34 have been amended.  
Claims 35-38, 46, 47, 63, 65, 70 and 81-84 have been cancelled.  
Claims 3-5, 9-12, 34, 39 and 62 are examined on the merits.

***Withdrawn Objection***

***Claim Objections***

2. The objection of claim 3 because of the following informality: it cites "...at least one protein biomarkers...", which was not grammatically correct has been withdrawn in light of Applicants submission of an amendment to the claim on February 11, 2008.

***Withdrawn Rejection***

***Claim Rejections - 35 USC § 112***

3. The rejection of claims 3-5, 34, 39 and 62 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter set forth on page 3, section 5(a) of the first action on the merits (FAOM) which applicant regards as the invention is withdrawn in light of Applicants' amendment to claim 3 setting forth correlation steps.

***Claim Rejections - 35 USC § 102***

4. The rejection of claims 3-5, 9-12, 39 and 62 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,650,291 (issued July 22, 1997/ IDS reference AC submitted September 7, 2004) is withdrawn in light of Applicants' amendments to claim 3.
5. The rejection of claims 3-5, 9-12, 39 and 62 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,650,291 (issued July 22, 1997/ IDS reference AC submitted September 7, 2004) is withdrawn in light of Applicants' amendments to claim 3.

***New and Maintained Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 3-5, 9-12, 34, 39 and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

Applicants have amended claim 3 to recite "wherein an increase in the levels of one or more of Markers II and III, or a decrease in the levels of one or more of Markers I, IV, V or VII is indicative that the subject has ovarian cancer." However, Applicants have not pointed out support for this recitation. The Examiner has reviewed the specification and does not note where support for this amendment is found. At best the Examiner notes on page 17, lines 19-24 of the specification there is the broad contemplation of "a marker can be a polypeptide ...present at an elevated level or at a decreased level in samples...". There is no mention of specific markers that correspond to an increase or decrease in levels as set forth in claim 3. Applicants should list the page and line numbers within the disclosure that are commensurate with the new amendment or delete the new matter.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. The rejection of claims 9-12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

a. Claims 9, 10 and 11 continue to be indefinite in the recitation "known biomarker". It is not clear if the markers set forth as Marker I-Marker V and Marker VII have already been established as ovarian cancer markers and what the recitation means. Applicants' arguments are concise and limited. They note they have amended

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claims for clarity, see page 5 of the Remarks submitted February 11, 2008. However, the cited claims have not been amended and the metes and bounds still cannot be determined. For the reasons of record the rejection is maintained.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. The rejection of claims 3-5, 9-11, 39 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by U. S. Patent Application Publication number 2003/0003479 A1 (effective filing date April 19, 2001) is maintained.

Applicants argue the publication does not anticipate the claimed method because the markers disclosed in the publication are nucleic acid markers and not polypeptide markers and secondly, the publication does not teach or suggest the identification and/or [quantitation] of protein biomarkers, see page 6 of Remarks, 2nd paragraph. Moreover, Applicants assert “even if... the... publication did teach [the] biomarkers..., none of the nucleic acid markers disclosed correspond to the protein biomarkers set

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forth in the pending claims.", see Remarks, see Remarks, page 6, paragraph 4. These points of view and arguments have been carefully considered, but found unpersuasive.

The patent application publication discloses methods of detecting, characterizing and staging ovarian cancers comprising correlating changes in the levels of expression of marker genes with the presence of ovarian cancer, see abstract. The level of expression of the marker gene in a sample reads on detecting a protein encoded by a marker gene, or a polypeptide, see page 3, sections 0018 and 0019; claims 1-8 and 17-25. It is art known kD or kilodalton references proteins and not nucleic acids, hence the kDs cited beside the ovarian markers read on the atomic mass of the protein biomarkers.

Markers O49 (34 kD) and O82 (55 kD) are biomarkers that have molecular weights synonymous with Applicants' markers, Marker IV (of about 39.8 kD) and Marker V (of about 54 kD), respectively, see page 36.

Marker O316 (58kD) is a biomarker that has a molecular weight of about 54 kD and 60 kD, which corresponds to Marker V and CA 125, respectively, see page 39.

Markers O426 (52 kD) and O452 (36kD) are protein biomarkers having a molecular weight of about Marker V (54 kD) and Marker IV (39.8 kD), respectively, see page 40.

The publication's markers O504 (58 kD), O512 (40 kD) and O517 (72 kD) are within the range of Applicants' Markers V, IV and VII, respectively, see page 41.

A variety of formats can be employed to determine whether a sample contains a biomarker, see page 29 - page 32.

Applicants further arguments remarking the disclosed protein have masses that are from 0.5% to 14.5% and different the protein biomarkers cited in the claims, see page 7, 6<sup>th</sup> paragraph. Applicants' claims read on molecular weights of about or within a range. All of the disclosed markers read on the protein biomarkers Applicants have cited. The rejection is maintained for the reasons established herein and of record.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The rejection of claims 3-5, 9-12, 34, 39 and 62 under 35 U.S.C. 103(a) as being unpatentable over U. S. Patent Application Publication number 2003/0003479 A1 (effective filing date April 19, 2001), and further in view of U. S. Patent Application Publication number 2003/0137106 A1 (effective filing date March 9, 2001) and U.S. Patent 5,650,291 (issued July 22, 1997/ IDS reference AC submitted September 7, 2004) is maintained.

Applicants argue the '479 publication does not teach or suggest the use of protein biomarkers for the detection of ovarian cancer and the proteins of the publication are not the same molecular weights as the biomarkers in the instant claims, see page 8,



paragraph 2 of the Remarks. Applicants complete arguments asserting the secondary references do not make up for the deficiencies of the '479 publication, see 3<sup>rd</sup> paragraph. For the reasons presented in the 102(e) rejection the instant rejection is maintained.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

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If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.

23 April 2008

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643